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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ILLINOIS

MALKA ASHKENAZI, individually, as Personal Representative of the Estate of the Decedent ELI ASHKENAZI, as Guardian for the minor Plaintiff MOTI ASHKENAZI, and HADAS ASHKENAZI (an adult child of the Decedent), all citizens of Israel,

Plaintiffs,

v.

BAYER CORPORATION, an Indiana corporation, successor to CUTTER BIOLOGICAL, a California Corporation; BAXTER HEALTHCARE CORPORATION, a Delaware corporation, and its HYLAND DIVISION; BAXTER INTERNATIONAL, INC., a Delaware corporation, successor to IMMUNO – U.S., INC., a Michigan Corporation; ARMOUR PHARMACEUTICAL COMPANY, INC., a Delaware corporation; AVENTIS BEHRING LLC, a Delaware corporation, and AVENTIS INC., a Pennsylvania corporation; and ALPHA THERAPEUTIC CORPORATION, a California corporation

Defendants.

Case No.

COMPLAINT FOR DAMAGES AND INJUNCTIVE RELIEF

Jury Trial Demanded

(1) Wrongful Death

I. INTRODUCTION

1. Defendants manufactured blood products known as "Factor VIII" and "Factor IX" for the treatment of hemophilia, and sold these products to people with hemophilia in Israel and other foreign markets, despite knowledge that the products were manufactured from sick, high risk donors and/or known to be contaminated with the viruses that cause the Human Immunodeficiency Virus and Hepatitis C (now known as "HIV" or "HIV/AIDS" and "HCV" respectively). Defendants continued selling these products to people with hemophilia in Israel and elsewhere even after the products were no longer being used in the United States due to the known risk of HIV/AIDS and HCV transmission. As discussed more fully in paragraphs 66 - 69, Defendants, such as BAXTER/IMMUNO and CUTTER refused to recall old stocks of products they knew to be contaminated with HIV and HCV both in the United States and abroad even after they had introduced a safer product.

2. Plaintiffs' decedent, ELI ASHKENAZI ("Decedent") had hemophilia, resided in Israel, and contracted HIV and HCV through use of Defendants' contaminated products. Further, Defendants, such as BAXTER/IMMUNO and CUTTER allowed their untreated factor concentrate products to remain on the market in Israel for years after they were required to begin providing safer, treated factor concentrate products in the United States.

3. Defendants manufactured HIV and HCV-contaminated blood factor products at plants in the United States using human plasma taken from thousands of paid American donors, including populations then known to be at high risk of carrying blood-borne diseases, such as urban homosexuals, prisoners, and intravenous drug users. Defendants intentionally recruited urban homosexuals who had a history of viral hepatitis as plasma donors, despite regulations prohibiting the use of such donors and despite knowledge that the viruses that cause HIV/AIDS and HCV were blood-borne diseases prevalent in such populations. Defendants continued using plasma taken from high risk prison donors, including from prisoners at the notorious Angola prison in Louisiana, even after promising the FDA that they would cease

doing so. Through their trade associations, Defendants actively conspired to conceal these practices and to substantially delay product recalls and implementation of safety measures.

4. Defendants failed to fully and completely disclose the known risks of their products, including the risk of HIV/AIDS and HCV; failed to implement readily available screening tests that would have prevented HIV/AIDS and HCV by excluding contaminated plasma; failed to use available methods of treating plasma to kill viruses, including heat treatment and solvent detergent; and concealed and affirmatively misrepresented the extent of the health dangers of the diseases caused by the products. Defendants continued to ship non-heat treated product to Israel and other foreign markets even after ceasing to sell it in the United States, in order to maintain their profit margin on existing contracts and sell off remaining stock no longer marketable domestically. Defendants also continued to sell old stocks of product that had not been treated with solvent detergent both in the United States and abroad, even after introducing a safer product treated with solvent detergent, including stocks that Defendants knew or had reason to know were made from pooled blood contaminated with HIV and HCV.

5. Defendants' efforts to maximize profits came at the expense of the health and lives of thousands of people with hemophilia in Israel and elsewhere who were needlessly infected with HIV/AIDS and HCV, including Plaintiffs' Decedent.

II. JURISDICTION AND VENUE

6. Plaintiffs allege an amount in controversy in excess of $75,000, exclusive of interest and costs. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the Plaintiffs and the Defendants.

7. Pursuant to this Court's prior Order (attached here to as **Exhibit A**), this action should be administratively transferred to MDL 986, pending before the Honorable John F. Grady, since it involves allegations of injuries and damages including HIV, HCV and related complications and injuries as a result of exposure to Defendants' blood factor products.

8. Plaintiffs are informed and believe and upon such information and belief

allege that the unlawful, negligent and/or tortious activity alleged herein was carried out predominantly in the United States. Defendants recruited high risk paid donors in the United States and mixed plasma from such donors into the blood pool at their facilities in the United States. Defendants placed misleading labels on their products in the United States and made affirmative misrepresentations regarding their products' safety in the United States, which were relied upon by Plaintiffs and their medical providers. Defendants' decisions to recruit paid donors from high risk populations, to refrain from disclosing the known risks of their products, to forego implementing readily available procedures that would have prevented their products from transmitting HIV/AIDS and HCV, and to ship their products to Israel and other foreign markets even after they could no longer be used domestically were all made in the United States. Defendants' acts of conspiracy, including trade association meetings where they agreed to engage in wrongful conduct, also took place in the United States.

9. Plaintiffs are informed and believe and upon such information and belief allege that the vast majority of the evidence of the unlawful activity alleged herein is located in the United States. Documents showing Defendants' policies, practices, and decisions regarding recruitment of plasma donors, mixing of plasma into the blood pool at their facilities, labeling of their products, advertising and promotion of their products, disclosure or lack thereof of the risks posed by their products, implementation or lack thereof of procedures to prevent their products from transmitting HIV/AIDS and HCV, and shipment of their products to Israel and other foreign markets are located almost exclusively in the United States. The vast majority of witnesses who will testify to these policies, practices, and decisions are also located in the United States, and would not be subject to subpoena in other countries. The expert witnesses likely to be presented by both Plaintiffs and Defendants are also located in the United States.

10. Most of the relevant medical records regarding the claims of Plaintiffs are located in the United States or have already been brought to the United States and have already been produced to Defendants. Similarly, Plaintiffs have produced or are in the process of preparing for production in the United States Preliminary Patient Profile Forms ("PPPFs"). In

addition, witnesses to the Plaintiffs' damages, such as the Plaintiffs' family members, are willing to travel to the United States to testify.

11. Because the Plaintiffs in this action reside in Israel with a different legal system, litigation in their home country would be costly and inefficient. In addition, Israel is an inadequate alternative forum because of chronic and lengthy court delays, lack of open discovery, unavailability of legal theories, procedures, and remedies, and lack of subpoena power over physical evidence in the United States.

12. Plaintiffs are informed and believe and upon such information and belief allege that Defendants' unlawful activity was carried out largely in the United States, and, in significant part, in the Northern District of Illinois. Defendant ARMOUR PHARMACEUTICAL COMPANY had its only blood factor manufacturing and processing plant in Kankakee, Illinois, at all pertinent times. This plant was the location of many meetings regarding the processing and research and development of factor concentrates, including meetings in the early 1980s involving discussions about the possible use of solvent detergents in the manufacturing of blood factor concentrates. This plant was also the location of inspections by the United States Food and Drug Administration and Canadian authorities amid reports of viral infections being spread through the use of factor concentrates. In addition, at all times pertinent, ARMOUR PHARMACEUTICAL COMPANY had subsidiary Collection Centers, collecting blood from paid donors, in Illinois.

13. Defendants BAXTER HEALTHCARE CORPORATION ("BAXTER HEALTHCARE"), BAXTER INTERNATIONAL, INC. ("BAXTER INTERNATIONAL") and IMMUNO U.S., Inc. ("IMMUNO U.S.") had their headquarters in Illinois at all pertinent times. Defendant BAXTER HEALTHCARE also collected blood from donors in Illinois at all times pertinent, including from donors jailed in the Cook County Jail in the early 1980s.

14. Plaintiffs are informed and believe and upon such information and belief allege that considerable evidence of Defendants' unlawful activity is located, in significant part, in the Northern District of Illinois, where much of the unlawful activity was carried out.

15. Plaintiffs are informed and believe and on such information and belief allege that the conduct by Defendants that is relevant to the subject matter of this action took place primarily in their respective headquarters locations, or in other facilities within the States of Illinois and California giving these states significant contacts to the claims asserted by Plaintiffs and creating state interests such that the choice of either or each of these states' laws to govern the adjudication of this action is neither arbitrary nor fundamentally unfair, and Plaintiffs hereby consent thereto.

III. PARTIES

16. The Plaintiffs in this action are as follows:

17. Plaintiff MALKA ASHKENAZI, the surviving spouse of Decedent Eli Ashkenazi, who was a resident of Ness Ziona, Israel, and who had hemophilia, and who was infected with HIV and HCV as a result of infusing Defendants' contaminated factor concentrate and/or as a result of Defendants' conspiracy. Plaintiff's Decedent has already provided Defendants with a confidential Preliminary Patient Profile Form (PPF), with beginning Bates number L-PPF 00485; the PPF contains substantial additional information regarding Plaintiff's claim. Plaintiff MALKA ASHKENAZI resides in Israel.

18. Plaintiff MOTI ASHKENAZI is the minor child of the Decedent, and resides in Israel. Plaintiff MALKA ASHKENAZI is the lawful Guardian of the minor Plaintiff MOTI ASHKENAZI.

19. Plaintiff HADAS ASHKENAZI is the adult child of the Decedent, and resides in Israel.

20. The Plaintiff's Decedent, Eli Ashkenazi, was the beloved husband and father of the Plaintiffs and died on or about March 31, 2007, in Israel, as a direct and proximate result of use of Defendants' blood products and Defendants' conspiracy.

21. Plaintiff's Decedent contracted permanent injuries and diseases, including HIV/AIDS and HCV and associated symptoms and diseases, as a direct and proximate

result of use of Defendants' blood products and Defendants' conspiracy.

22. Plaintiff's Decedent would not have chosen to be treated with Defendants' blood products had he known of or been informed by Defendants of the true risks of using those products or the nature of the sources of the blood products.

23. Defendant CUTTER, the predecessor of Miles, Inc. and Defendant BAYER, was a California corporation headquartered in Berkeley, California at all pertinent times. At all pertinent times CUTTER and its successors Miles, Inc. and BAYER regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of anti-hemophilic factor (hereinafter referred to as "AHF") produced from such plasma, to which Plaintiffs' Decedent was exposed and which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and HCV.

24. Defendant BAYER, formerly Miles, Inc., is and was an Indiana corporation, authorized to do business in all 50 states and the District of Columbia. Miles, Inc. had its principal place of business operation in Elkhart, Indiana, while its successor BAYER has its principal place of business in Pennsylvania, with offices located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. At all pertinent times BAYER and its predecessors Miles, Inc., and CUTTER regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of anti-hemophilic factor (hereinafter referred to as "AHF") produced from such plasma, to which Plaintiffs' Decedent was exposed and which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and HCV.

25. Defendant BAXTER HEALTHCARE is a Delaware corporation, authorized to do business in all 50 states and the District of Columbia, with its principal place of business in Illinois, with offices located at One Baxter Parkway, Deerfield, Illinois 60015. At all times pertinent, Defendant BAXTER HEALTHCARE, and/or its HYLAND DIVISION, had its main manufacturing plant in Glendale, California. At all times pertinent, Defendant BAXTER HEALTHCARE, and/or its HYLAND DIVISION, and/or its wholly owned subsidiaries

Travenol Laboratories and Fenwal Laboratories, regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of AHF products produced from such plasma, which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and/or HCV.

26. Defendant BAXTER INTERNATIONAL is a Delaware Corporation, and owner and successor in interest to Immuno International A.G., and IMMUNO-U.S. (described hereinafter collectively as, "IMMUNO"). BAXTER INTERNATIONAL has its principal place of business in Illinois, with offices located at One Baxter Parkway, Deerfield, Illinois 60015, and, on information and belief, is the party liable for the injuries resulting from infusion with Immuno factor concentrates during the relevant period. In 1997, BAXTER INTERNATIONAL acquired all assets and liabilities of Immuno International A.G., an Austrian company that at all times pertinent sold AHF products to Israel and other foreign markets that were produced from human plasma derived from paid donors in the United States. Immuno International A.G. operated in the United States at all times pertinent through its wholly owned American subsidiary Immuno-U.S., located in Rochester, New York. IMMUNO operated 15 processing centers in the United States in the 1980s, which collected plasma from high-risk donors for fractionation in plants located in Rochester, Michigan and Vienna, Austria. These products were then shipped all over the world, and contributed directly or indirectly to Plaintiffs' infection with HIV and HCV. IMMUNO's product names, Bebulin, Feiba, and Prothromplex, are now listed as BAXTER INTERNATIONAL products in the 2003 Registry of Factor Concentrates put out by the World Federation for Hemophilia.

27. IMMUNO – U.S. was a Michigan corporation and was at all pertinent times a United States based operating subsidiary of Immuno International A.G. The most recent corporate filing for IMMUNO – U.S. is the 1998 certificate of merger filed by BAXTER, listing the principal place of business for the surviving entity as One Baxter Parkway, Deerfield, IL 60015, the same address for Defendants BAXTER INTERNATIONAL and BAXTER HEALTHCARE.

28. Defendant ARMOUR PHARMACEUTICAL COMPANY, INC., is a Delaware corporation, authorized to do business in all 50 states and the District of Columbia, with its principal place of business in Pennsylvania, with offices located at 500 Arcola Road, P.O. Box 1200, Collegeville, Pennsylvania 19426-0107. In 1996 Defendant ARMOUR merged with Behringwerke A.G., a Israeli company that at all times pertinent sold AHF products which were produced from human plasma derived from paid donors in the United States, to form Defendant AVENTIS BEHRING LLC, formerly Centeon Bio-Services, Inc., a Delaware company with offices located at 1020 First Avenue, King of Prussia, Pennsylvania, 19406. Defendant AVENTIS BEHRING LLC and its predecessors, Centeon Bio-Services, Inc. and Armour Plasma Alliance, Inc., are wholly owned subsidiaries of Defendant AVENTIS INC., formerly Rhone-Poulenc Rorer International, Inc., formerly Rorer Group, Inc., a Pennsylvania corporation authorized to do business in all 50 states and the District of Columbia, with offices located at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey, 08807. At all times pertinent, Defendants ARMOUR PHARMACEUTICAL COMPANY, INC., AVENTIS BEHRING LLC, and AVENTIS INC., (all of whom are described hereinafter collectively as "ARMOUR") regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of AHF products produced from such plasma, to which Plaintiffs' Decedent was exposed and which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and/or HCV.

29. Defendant ALPHA THERAPEUTIC CORPORATION (hereinafter "ALPHA") is a California corporation authorized to do business in all 50 states and the District of Columbia, with its principal place of business in California, with offices at 5555 Valley Boulevard, Los Angeles, California 90032. At all times pertinent Defendant ALPHA has been regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of AHF products produced from such plasma, to which Plaintiffs were exposed and which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and HCV.

30. Defendants CUTTER, ARMOUR, BAXTER HEALTHCARE, BAXTER INTERNATIONAL, IMMUNO, (BAXTER HEALTHCARE, BAXTER INTERNATIONAL, and IMMUNO shall hereinafter be collectively referred to as "BAXTER") and ALPHA (herein collectively identified as "MANUFACTURERS" or "DEFENDANTS") acting on behalf of themselves and/or their predecessor and/or successor corporations, collected, harvested and/or processed human plasma and/or manufactured, marketed, sold and distributed factor concentrate products to Israel and other foreign markets that were contaminated with HIV/AIDS and/or HCV. In the alternative, one or more of said Defendants participated in the collection, harvesting and/or processing of human plasma and/or the manufacturing, marketing, distribution and sale of factor concentrate products to Israel and other foreign markets, or assumed, became or are responsible for the liabilities of the Defendants and their predecessor or successor corporations who did participate in the collection, harvesting and/or processing of human plasma and/or the manufacturing, marketing, distribution or sale of factor concentrate products to Israel and other foreign markets, without limitation thereto.

31. At all times herein mentioned, all Defendants and each of them, were fully informed of the actions of their agents and employees, and thereafter no officer, director or managing agent of Defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions and that all Defendants and each of them, thereby ratified those actions.

IV. FACTUAL ALLEGATIONS APPLICABLE TO ALL CLAIMS

A. Hemophilia and Its Treatment

32. Hemophilia is an inherited condition that causes uncontrolled hemorrhaging or bleeding. Hemophilia results from a deficiency of blood components essential for coagulation. The most common form of the disease is hemophilia A, characterized by a lack of a blood protein known as Factor VIII, which affects approximately one in 10,000 males. Factor VIII is commonly called "AHF," or anti-hemophilic factor. Hemophilia B is characterized

by absence of another blood protein, known as Factor IX, affecting about one in 40,000 males. Von Willebrand's disease is an inherited hemorrhagic condition similar to hemophilia that affects both men and women. It is characterized by lack of both Factor VIII and another blood protein called von Willebrand's factor.

33. The treatment of hemophilia and von Willebrand's disease involves intravenous introduction, called infusion, of the missing blood proteins required to stop bleeding. The two most prevalent forms of such treatment are cryoprecipitate, and factor concentrates. Factor concentrates are the product made by Defendants in this action. Cryoprecipitate is made by freezing plasma, the fluid component of circulating blood in which various proteins, including Factor VIII and Factor IX, are contained; thawing the frozen plasma; and isolating Factor VIII from the plasma through centrifugal concentration. Cryoprecipitate is an effective therapeutic agent for patients with hemophilia A. Hemophilia B has been effectively treated with the use of fresh frozen plasma containing Factor IX. Cryoprecipitate and fresh frozen plasma are made from small numbers of donors, who are generally unpaid volunteers.

34. By contrast, Defendants in the late 1960s to early 1970s began to market factor concentrates, or AHF, which contained Factor VIII and Factor IX in higher concentrations than had been available in either cryoprecipitate or fresh-frozen plasma. To produce factor concentrates, Defendants mixed pools of plasma from five to twenty thousand donors at a time, a substantial percentage of which were paid donors. These large pools were then subjected to chemical process to concentrate Factors VIII and IX.

B. Even Before the Discovery of HIV and AIDS, Defendants Failed to Disclose or Warn of Serious Adverse Effects Associated with Factor Concentrates

35. Shortly after the initial commercial marketing of Factor VIII and IX concentrates in the late 1960s to early 1970s, a wide range of serious adverse effects were reported in association with these products. Even before the dissemination of HIV, Defendants knew of serious diseases caused by unidentified agents transmissible by blood and Factor VIII and IX. Defendants failed to warn Plaintiffs, Plaintiffs' Decedent or the medical community of

these adverse effects, in violation of industry standards and federal regulations.

36. By 1976, only a few years after Defendants' factor concentrate products went on the market, the United States Food and Drug Administration ("FDA") Bureau of Biologics held a conference entitled "Unsolved Therapeutic Problems in Hemophilia." The research articles compiled from the conference discussed the high incidence in patients using Defendants' products of disorders such as liver dysfunction, enlarged spleen, Hepatitis B, and Non-A, Non-B Hepatitis ("NANB Hepatitis," later renamed Hepatitis C). The articles concluded that these disorders were tied to the patients' use of factor concentrates, and emphasized the risks entailed in producing such concentrates using plasma from paid donors. As described below, however, Defendants not only refused to implement such a voluntary donor system, but instead recruited paid donors precisely because their hepatitis exposure resulted in plasma from which Defendants could make other commercially valuable products as well.

37. Several of the articles from the 1976 conference also raised alarm over the unprecedented convergence of immune disorders in the hemophiliac community, and called for close medical monitoring of the situation.

38. At all times material to this Complaint, Defendants failed to adequately warn Plaintiffs, Plaintiffs' Decedent, or his physicians of these serious adverse side effects. Several such adverse effects, including immunosuppression (suppression of the immune system) were not mentioned at all in the Defendants' package inserts, which were required to disclose adverse reactions pursuant to federal statutes and regulations and applicable standards of care. Although Defendants' inserts mentioned a risk that plasma "may" contain the causative agent of viral hepatitis, the warning was seriously deficient in that: (a) Defendants failed to disclose that the risk of hepatitis was essentially a 100% guarantee due to their practices of using high-risk donors and specifically recruiting for donors who had previously been exposed to Hepatitis B; (b) while "hepatitis" simply means inflammation of the liver, and may be a relatively benign, temporary condition, Defendants failed to warn that some forms of hepatitis transmitted by their products were believed to present a considerable risk of severe liver damage, cirrhosis, and

significantly elevated risk of cancer; (c) Defendants misleadingly stated that the source plasma used in preparation of the product had been found to be non-reactive for Hepatitis B surface antigen (HBsAg)—implying that no viral hepatitis was present in the plasma—and falsely stated that available methods were not sensitive enough to detect all units of potentially infectious plasma, while failing to disclose that Defendants had refused to implement the more sophisticated Hepatitis B Core Antibody (HBc) test which would have excluded essentially all plasma contaminated by Hepatitis B; and (d) Defendants' labeling disclosed that the product was made from large pools of fresh human plasma, but failed to disclose that paid donors increased the risk of disease, and that the particular groups of paid donors targeted by Defendants were known to be the highest risk groups available.

C. Defendants Recruited Plasma Donors from High Risk Populations to Manufacture Factor VIII and IX

39. The demand for and supply of anti-hemophilia factor rapidly increased during the 1970's, with the commercially-manufactured concentrate accounting for a large proportion of the increase in supply. In 1977, a federal report projected that the volume of AHF manufactured would increase substantially by 1980. ("Study to Evaluate the Supply-Demand Relationships for AHF and PTC Through 1980," Division of Blood Diseases and Resources, National Heart, Lung and Blood Institute (1977), at page 8; hereinafter "NHLBI Report").

40. In order to sell more AHF to this growing market, Defendants turned to the fastest and cheapest way of obtaining sufficient plasma, paid donors. Defendants recruited paid donors from those populations most likely to respond to the financial incentive to donate: poor inner city residents, drug abusers, prisoners, and even residents of impoverished developing countries such as Haiti and Nicaragua.

41. Defendants purposefully sought out paid donors despite knowing that the risk of diseases transmissible by blood was far greater among paid donors than among volunteers. Because no test was available yet for the NANB Hepatitis virus identified in the early 1970's, the only means to prevent the virus from contaminating the plasma supply was to

exclude donors with behaviors that were inconsistent with good health—precisely those populations from which Defendants were recruiting paid donors. Some studies indicated that paid donors were up to ten times more infectious than volunteer donors. For this reason, the National Blood Policy, adopted by the federal government in July 1973, advocated conversion to an all-volunteer blood supply. Defendants, however, not only continued to use paid donors, but also focused their recruiting efforts on the highest risk populations.

42. Defendants had an additional financial incentive for recruiting paid donors. Factor VIII and Factor IX are only two of many products that can be made for commercial sale from human plasma. According to the NHLBI Report, by the late 1970s at least 17 different therapeutic components of blood were manufactured by the process of "fractionating" plasma into its various elements. The NHLBI Report noted that, "as the costs of fractionation have increased, fractionators have produced as many products as possible from a liter of plasma." (Id. at 65).

43. Blood derivatives used as vaccines or therapeutics had particularly high economic value for Defendants. The NHLBI Report noted that plasma with a very high titer, or antibody level, for a corresponding antigen is "very expensive." (Id. at 41). Such products are manufactured from source plasma drawn from donors who have been sensitized to a particular antigen. (Id.). The NHLBI Report specifically stated, however, that "plasma collected for high antibody titer cannot be used for fractionation into therapeutic products," such as Defendants' factor concentrate. (Id., emphasis added).

44. Defendants targeted donors with high titers to Hepatitis B antigens in order to manufacture and sell Hepatitis B immunoglobulin (HBIG), a product that confers temporary immunity to the Hepatitis B virus. Despite the warning in the NHLBI report, Defendants' used the same high titer plasma they obtained for making HBIG to manufacture the Factor VIII and IX products used by people with hemophilia. Defendants thus sought to maximize profits by producing "as many products as possible from a liter of plasma," while ignoring industry standards that precluded the use of high-titer plasma for other therapeutic

products.

45. Beginning in about 1978, Defendants BAXTER, CUTTER and ALPHA began targeting homosexual donors in known urban gay communities. Because urban homosexuals had been reported in the 1970's to have exceptionally high prevalence of Hepatitis B infection, Defendants knew that such donors would provide a reliable source of plasma for the manufacture of commercially valuable HBIG.

46. It was also well-known in the public health community by the 1970's that urban homosexuals engaged in promiscuous sexual practices that rapidly transmitted other diseases, including NANB Hepatitis, which were transmitted by blood, could not be isolated nor identified, and were believed to have serious adverse consequences. Despite this knowledge, Defendants used the same plasma pool from urban homosexuals to manufacture both HBIG and Factor VIII and IX.

47. Defendants continued this dual use of high risk plasma even after federal reports warned of the rapid spread of fatal immunosuppressive disease among the same homosexual population from which Defendants heavily recruited. Defendants knew or should have known by no later than the summer of 1981 that urban homosexual males were not "suitable donors" within the meaning of federal regulations and/or other applicable standards of care.

48. By the 1970s, it was also well-established that plasma from prison populations carried a high risk of hepatitis and other blood-borne diseases, primarily because of the concentration of intravenous (IV) drug users in prisons. Despite knowledge of this risk, Defendants actively recruited prisoners for plasma used to manufacture Factor VIII and IX, while concealing or failing to disclose the risk to Plaintiffs, Plaintiffs' Decedent, his physicians, or the FDA.

49. In light of Defendants' special knowledge of the disease patterns among urban homosexuals and prisoners, and their recruitment of such donors for Factor VIII and IX manufacture, Defendants had duties to: (a) promptly investigate the first reports of opportunistic

infections among urban homosexuals in 1981; (b) discontinue the practice of using such high risk donors; (c) disclose the risk to Plaintiffs, Plaintiffs' Decedent, his physicians, and the FDA, including the ongoing risk of continuing to use Factor VIII and IX previously manufactured with high risk plasma and still marketed to patients; (d) implement procedures to kill blood-borne diseases in the products; and (e) recall existing products from distribution or further use. Instead, Defendants continued to conceal their recruitment of high risk donors and resist warnings and recalls, and failed to implement procedures to make their products safe.

D. Defendants Failed to Use the Available Hepatitis B Core (HBc) Test to Exclude Plasma from High Risk Donors

50. By no later than 1978, Defendants knew of the availability of a new test to determine whether an individual had a history of viral Hepatitis, which would have disqualified the donor from providing plasma for the manufacture of Factor VIII or IX. By testing a person's serum for the presence of the core to the Hepatitis B antibody, a history of viral Hepatitis could be verified. This was known as the "HBc test." Published, peer-reviewed literature shows that the HBc test was in use by researchers to determine that homosexual AIDS victims had a history of viral Hepatitis by no later than December 1981. (Gottlieb, et al., "Pneumocystis Carinii Pneumonia and Mucosal Candidiasis in Previously Healthy Homosexual Men," NEW ENGLAND JOURNAL OF MEDICINE 1981; 305:1425-1431).

51. Use of the HBc test would have eliminated approximately 75% of homosexual plasma donors and over 90% of promiscuous urban homosexuals. It would have eliminated almost 100% of intravenous drug users.

52. Use of the HBc and ALT tests by Defendants by 1981 would have eliminated the vast majority of the transmitters of HIV and HCV from the blood and plasma pools of the nation, before the height of the AIDS and Hepatitis C epidemics. If Defendants had implemented this test in a timely manner, Plaintiffs' Decedent would never have been infected with HIV or HCV as a result of factor concentrate use.

53. Plaintiffs' Decedent and thousands of other people with hemophilia in

Israel and other countries became infected by the AIDS and Hepatitis C viruses through repeated exposures from blood products manufactured from large pools of plasma donors (5,000 to 40,000). If Defendants had used the HBc and ALT tests to decrease by 70% to 90% the number of HIV and HCV positive donors who went into a pool, the infectivity of the product would have decreased substantially. Consequently, the rate of infection of people with hemophilia would have slowed down enormously, and the medical and scientific community would have been given more time to react appropriately to the HIV and Hepatitis C epidemics.

54. As noted below, federal regulations required plasma donors to be in good health, and donors with a "history of viral Hepatitis" were by definition unacceptable as blood or blood plasma donors. Persons with a history of viral hepatitis were excluded not only because of the risk of transmitting Hepatitis B, but because such a history indicated a lifestyle or previous behavior of the prospective donor which carried the risk of transmitting other viruses in addition to hepatitis. A reasonable and prudent plasma fractionator would not accept a HBc positive donor and expect to be in compliance with federal regulations as of 1978.

55. After public reports of the first hemophilia AIDS cases in July 1982, government officials urged Defendants to implement the HBc test as a "surrogate" or "marker" to eliminate plasma contaminated by the transmitter of AIDS or Hepatitis C. HBc testing was also strongly suggested to Defendants by the CDC at a meeting of the United States Public Health Service ("PHS") on January 4, 1983. Despite this urging, Defendants continued to use contaminated plasma donations that would have been excluded by the HBc test and continued to conceal from Plaintiffs, Plaintiffs' Decedent, his physicians, and the FDA the dangerous practice of targeting donors at highest risk for the very diseases that disqualified their plasma. At a January 6, 1983 meeting of Defendants' trade association, the Pharmaceutical Manufacturer's Association, Defendants agreed not to implement the highly effective HBc donor screening, and instead opted to use ineffective donor questionnaires that did little to screen out donors at high risk for AIDS and Hepatitis C transmission.

56. As late as December 13, 1983, years after the HBc test was available, a

memorandum from CUTTER's responsible head Stephen Ojala to various CUTTER executives, reporting back on a meeting held by all Defendants, shows that all Defendants conspired to propose a "task force" to further study the use of HBc as an intentional, bad faith "delaying tactic for the implementation" of the test.

E. Defendants Also Failed to Implement Available Heat Treatment and Solvent Detergent to Kill Blood Borne Diseases

57. In the late 1970s and early 1980s, it was recognized that viruses were in all AHF products, including Factor VIII and IX. Heat treatment and solvent detergent was available at that time to eliminate many of these viruses, including HIV and HCV. Defendants were required to take reasonable steps to eliminate contamination, but Defendants failed to utilize these available technologies to eliminate the viruses in a timely manner.

58. The 1977 NHLBI Report noted that albumin, another plasma product, was "heat treated to remove almost all danger of hepatitis." (Id., at p. 49). Defendant ARMOUR'S memorandum of June 1983 acknowledged that no cases of AIDS had been reported in heat--treated albumin users, but misleadingly states that heat treatment of Factor VIII and IX was not yet feasible. It was clearly known by no later than 1977 that heat treatment was an effective way to make blood products safer, but Defendants wrongfully refused to implement such procedures as to Factor VIII and IX. In 1995, the National Institutes of Health Institute of Medicine ("IOM") issued a report on the hemophilia AIDS epidemic which concluded that defendants "did not seriously consider alternative inactivation processes," including heat treatment, and that "heat treatment processes to prevent the transmission of hepatitis could have been developed before 1980." Heat treated, HIV-safe factor concentrates were not introduced by any Defendant until 1983, and were not universally in use until 1985.

59. In addition to heat treatment, solvent detergent treatment was available to Defendants by the late 1970's as a simple and effective method of eliminating viruses in their factor concentrate products. Solvent detergent effectively kills viruses such as HIV and HCV by destroying the viruses' lipid envelope. It is simpler than heat treatment, and unlike heat treatment

does not interfere with the Factor VIII and IX proteins needed for blood clotting.

60. Solvent detergents were well-known, commercially available products as of the 1970's, and studies in which solvent detergent treatment was used to disrupt viruses were published in the 1970's in peer-reviewed journals. In 1980, Dr. Edward Shanbrom, a former BAXTER scientist, received a patent for a solvent detergent treatment process for viral inactivation of factor concentrate. Dr. Shanbrom describes the implementation of this process as "as easy as washing your hands."

61. After receiving the patent, Dr. Shanbrom approached various Defendants about implementing the solvent detergent method, but these Defendants wrongfully refused to implement the method. Several of the Defendants refused to even commit any resources to investigate the method. However, in June, 1985, the New York Blood Center ("NYBC") obtained a license from the FDA to implement the process for Factor VIII. The NYBC obtained a license to use the process in 1987. On information and belief, by 1987, all Defendants except ARMOUR were using the process to virally inactivate their Factor VIII blood products.

62. Although heat treatment was effective in destroying the HIV virus, it was ineffective in destroying HCV and HBV. A recent CDC study reported that "84% of previously untreated patients infused with dry-heated Factor VIII products developed non-A, non B hepatitis ... several case reports of probable transmission of HBV and HCV through vapor heat-treated and pasteurized products later appeared." (Risk Factor for Infection with HBV and HCV in a Large Cohort of Hemophiliac Males: Soucie, Richardson, Evatt et al; Transfusion, 2001; 41:338-343)

63. The same CDC study reported that "solvent detergent treatment of blood components found to be more effective against enveloped viruses than heat treatment ... No cases of HBV, HCV, or HIV transmission through solvent detergent virus inactivated products have been found in prospective studies of previously untreated patients..."

64. The study further reported "in our data, the first dramatic decline in HCV prevalence appears in the 1987 birth cohort. The drop in HCV transmission correlates with the

licensing of solvent detergent treatment of factor IX products in 1987. In addition, this cohort would have been the first to benefit from the screening of blood donors using the surrogate markers ALT (begun in late 1986) and anti-HBc (begun in 1987), testing that was associated with a markedly decreased risk of HCV infection from blood transfusions."

65. The study states further that "the residual transmissions after 1987 possibly represent the use of product already manufactured or product manufactured during the interval required to implement the new technology. The 18-month shelf life of factor concentrates placed those people with hemophilia born as late as 1989 at risk of infection." The study goes on to recommend testing for all people with hemophilia who received infusions of the defendant's blood products prior to 1992.

66. The failure of Defendants to implement solvent detergent viral inactivation techniques in a timely manner, to warn of the risk that heat treated Factor VIII and IX blood products could transmit HBV and HCV, and to recall heat treated products that posed this risk caused the needless infection of thousands of people with hemophilia with HCV and HBV after 1983, including Plaintiffs' Decedent. Even after Defendants knew or should have known that the solvent detergent process effectively destroyed HCV and HBV, as well as HIV, they continued to sell heat treated Factor VIII and IX, and refused to recall these dangerous products from the market.

F. Defendants Continued to Allow the Sale of Non-Heat Treated Factor Concentrate Products Abroad Even After They Stopped Selling Non-Heat Treated Product in the United States

67. Between 1983 and 1985, Defendants stopped selling non-heat treated factor concentrate in the United States and introduced a vastly safer heat-treated version. However, one or more Defendants, including BAXTER/IMMUNO and CUTTER continued to allow their remaining stocks of non-heat treated product to remain on the market in Israel and other countries after ceasing sales of such product in the United States, despite knowledge that the non-heat treated product was contaminated with HIV and/or HCV.

68. As detailed in this Complaint, by the end of 1982 Defendants' internal communications in the United States revealed their awareness of the AIDS risk posed by their products, but they continued to disavow the connection between AIDS and factor concentrates in their communications to foreign doctors and persons with hemophilia. In mid-1983, months after CUTTER executives authored internal memos expressing their belief that factor concentrates transmitted AIDS, the company wrote a letter to its foreign distributors, in which it characterized the concern over AIDS as an "irrational response," and dismissed the notion that AIDS could be transmitted by factor concentrates as "unsubstantiated speculation." (Internal Defendant documents) CUTTER told the distributors that "[w]hat little evidence exists . . . tends to suggest that AHF concentrates have no direct role in [the AIDS] syndrome."

69. Even after Defendants introduced heat-treated products that did not transmit HIV and touted the safety of these new products, they continued selling their contaminated non-HT product abroad.

70. In October of 1984, the CDC issued a report announcing that 74% recipients of Factor VIII concentrates made from plasma derived from American donors were HIV positive. CDC data supports the role American factor played in spreading AIDS among Plaintiffs' Decedent and other persons with hemophilia in Israel. The CDC report also publicized studies showing that heat treatment effectively killed the HIV virus. Upon information and belief, Defendants did not upon receiving this news recall or withdraw their unheated products from Israel. Such products therefore remained on the shelves and continued infecting Israeli hemophiliacs until their expiration dates.

G. Defendants Fraudulently Misrepresented the Safety of Factor VIII and IX and Concealed the Dangers of the Products

71. Defendants engaged in a pattern and practice of fraudulent concealment of their dangerous practices, fraudulent misrepresentations of the extent of their efforts to assure safety, and fraudulent misrepresentations that understated the risk of AIDS and Hepatitis C, in order to maintain profits from both factor concentrates and HBIG. A summary of Defendants'

fraudulent misrepresentations and concealment is set forth below.

72. On July 27, 1982, a meeting of the Public Health Service was held as the result of the CDC's report of three people with hemophilia who contracted AIDS. The responsible heads of ARMOUR, ALPHA, CUTTER and BAXTER HEALTHCARE were in attendance, along with officials from the National Hemophilia Foundation, CDC and FDA. At least three of the Defendants were aware that they had used cryoprecipitate containing plasma from known, targeted homosexuals in the manufacture of Factor VIII and IX blood products. These products had a shelf life of two and three years, respectively, and were either in production or already on the shelves in pharmacies waiting to be infused by people with hemophilia who purchased them. The Defendants involved, CUTTER, BAXTER and ALPHA, failed to disclose these facts at the meeting where CDC officials Dr. Don Francis and Dr. Jeff Koplin were present, despite knowledge that the CDC's primary concern at that meeting was the infection of Factor VIII and IX by the transmitter of AIDS, which was already well-known to be epidemic in the targeted homosexual population. (CUTTER memorandum dated August 3, 1982)

73. In or about December, 1982, Rodell, the responsible head for BAXTER HEALTHCARE, entered into an agreement with officials of the FDA to the effect that BAXTER HEALTHCARE would no longer use prison plasma in the production of factor concentrates. In fact, BAXTER HEALTHCARE, unbeknownst to the FDA, continued to use prison plasma in factor concentrate production through October 1983. (BAXTER HEALTHCARE memorandum dated October 20, 1983.)

74. On January 5, 1983, an AIDS meeting was held at Children's Orthopedic Hospital in Los Angeles, California, the largest hemophilia treatment center in the United States. Representatives of four Defendants were present at the meeting with treaters and patients. The purpose of the meeting was to have Defendants' representatives answer patients' questions about AIDS transmission through factor concentrates. A patient asked representatives from CUTTER, ALPHA, ARMOUR and BAXTER the following question: "Is the plasma from homosexuals, prisoners, Haitians or other high risk persons being used in the manufacture of concentrates?" No

Defendants admitted targeting or using plasma from homosexuals, prisoners or inner city IV drug abusers. Dr. Goodman from BAXTER HEALTHCARE answered regarding BAXTER HEALTHCARE'S use of known homosexuals as follows: "We are changing the nature of questions to homosexuals to the best of our ability." CUTTER'S responsible head, Stephen Ojala, an ALPHA representative, and ARMOUR'S Karl Hansen made no response to the question. This partial and misleading response amounted to concealment of the true risk created by the use of known homosexuals, IV drug abusers and prisoners in the manufacture of factor concentrates.

75. At the January 5, 1983 meeting, and in the presence of the patients, one of the treating physicians, Dr. Kasper, asked CUTTER'S Stephen Ojala: "These [plasma] centers seem to be in rundown centers of town. Is there a move to move them to rural towns?" Ojala answered: "Many of the centers are in smaller communities and in towns such as Ypsilanti, Seattle, Clayton, NC., and San Diego. We do not have centers in L.A. or San Francisco." This answer was misleading because Ojala failed to state that CUTTER'S largest and first plasma center was located at Arizona State Penitentiary. CUTTER also had a center at the Las Vegas Prison. Ojala and CUTTER were well aware of the CDC's and FDA's concern over use of prison plasma, due to homosexual practices and drug abuse in the prison donor population. Many of CUTTER'S centers were in inner city areas frequented by IV drug abusers, such as downtown Oakland, California. CUTTER had also used plasma from centers which targeted known homosexuals. In August 1982, CUTTER quarantined plasma from the Valley Medical Center, a center which targeted known homosexuals, because a donor was hospitalized with full blown AIDS. The plasma was intended for Factor IX and HBIG production, but was not used because it had thawed on the way to the processing plant. Upon receiving a report of this incident from CUTTER, the FDA indicated a recall might have been necessary if the plasma had been incorporated into factor concentrate final product. Ojala omitted any mention of these facts and circumstances in his response to Dr. Kasper regarding the location of their plasma centers. (CUTTER memorandum dated January 5,1983.)

76. On January 14, 1983, Dr. Michael Rodell and the other responsible heads from Defendants attended a meeting of the National Hemophilia Foundation ("NHF"). The purpose of the meeting was to have Defendants explain to the NHF what steps they were prepared to take to safeguard the plasma supply from potential AIDS transmitters. Defendants were very concerned that the NHF would insist on a recommendation that HBc testing be implemented, consistent with the CDC recommendation 10 days earlier. BAXTER HEALTHCARE, under Rodell's supervision, had already conducted a survey of several of their donor centers to determine how many donors they would lose if the test were implemented. BAXTER HEALTHCARE had decided that up to 16% of their donors would not pass the test. Further, BAXTER HEALTHCARE'S high titered immunoglobulin donors would be eliminated. In order to defer an NHF recommendation that HBc testing be used, Rodell told NHF officials that surrogate testing was in the "R and D," or "Research and Development," stage currently. Rodell concealed the fact that the CDC had strongly recommended use of the HBc Antibody test as a screening device for donors at high risk for AIDS transmission. The HBc Antibody test was not in the "R and D" stage, and was suitable for use as a screening device for high risk AIDS and Hepatitis C donors. In fact, the HBc test had been approved in 1979 by the FDA as a diagnostic test to be used to ascertain a history of previous hepatitis B infection, and as a screening device for blood and plasma donors. The test had the capability of identifying all donors with a history of viral hepatitis. Donors with a hepatitis history were specifically prohibited pursuant to the federal regulations (21 C.F.R. § 640.63). Rodell acknowledged that implementation of the HBc test would eliminate high titered immunoglobulin donors, but failed to disclose that opposition to use of the test was based on economic rather than safety concerns.

77. At the January 14, 1983 meeting, ALPHA, CUTTER and BAXTER concealed their advertising in publications distributed among urban homosexuals, for the specific purpose of attracting them to plasma centers which supplied high titered plasma to the Defendants. CUTTER and ALPHA concealed their extensive use of prison plasma, and BAXTER discussed plans to phase out prison plasma during the coming year. However, none of

the Defendants revealed their "gentlemen's agreement" with the FDA to discontinue use of these plasma sources immediately. (CUTTER Memorandum dated January 17, 1983.)

78. On or about December 15, 1983, Rodell, then the head of ARMOUR, told members of the federal Blood Product Advisory Committee (BPAC) and FDA officials that the Defendants wanted a three month deferral in implementation of any recommendations by the BPAC or FDA that HBc testing be required for plasma donors. Rodell told the FDA that the purpose of the deferral was to prepare a response to the proposed recommendation. In fact, the Defendants had agreed to seek the three month hiatus as a "delaying tactic" against implementing the test, and the request for a deferral was made in bad faith. (CUTTER memorandum dated December 13, 1983.)

79. It was strongly suggested by the CDC on July 27, 1982, that AIDS had a viral etiology similar to Hepatitis B because of the risk groups involved. These risk groups comprised a substantial portion of CUTTER'S plasma donor sources. CUTTER took no meaningful action to screen out donors at the highest risk for AIDS and Hepatitis C transmission at any time during the epidemic. In fact, they continued to market products containing plasma from these groups throughout 1982, 1983 and 1984 worldwide. Even more egregiously, CUTTER and other Defendants continued to market high risk non-heat treated factor concentrate abroad after ceasing sales of such product in the United States in favor of vastly safer heat treated product.

80. Defendants, jointly and individually, fraudulently misrepresented the risk of AIDS and Hepatitis C due to factor concentrates, failed to disclose accurate warnings of the risk to Plaintiffs, Plaintiffs' Decedent or his physicians, and fraudulently purported to be doing "everything possible" to improve safety, when in fact Defendants maximized the risk by recruiting high risk donors and by resisting and obstructing HBc testing, heat treatment, and other measures that would truly have reduced the risk.

H. Defendants' Activities Were Subject to Applicable Federal Regulations, Which Evidence the Standard of Care With Which Defendants Should Have Complied

81. Blood derivatives such as Factor VIII and IX are prescription biologicals subject to federal regulation as both "biological products" and "drugs." Public Health Service Act, "Regulation of Biological Products," 42 U.S.C. § 262; Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*

(a) 21 U.S.C. § 331(b) prohibited "adulteration or misbranding of any … drug, ..."

(b) 21 U.S.C. § 351(a)(2)(B) provided that "[a] drug . . . shall be deemed to be adulterated . . . if . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety. . . ."

(c) 21 U.S.C. § 352 provided that "[a] drug... shall be deemed to be misbranded. .. if its labeling is false or misleading in any particular."

(d) 21 U.S.C. § 352(f)(2) provided that a drug shall be deemed to be "misbranded" unless its labeling bears "adequate warnings against use. .. where its use may be dangerous to health."

(e) 21 U.S.C. § 352(n) provided that a drug shall be deemed to be "misbranded" unless the labeling included information concerning side effects and contraindications as required in federal regulations.

(f) 21 U.S.C. § 321(n) provided that if an article is alleged to be misbranded because the labeling or advertising is misleading, then the determination of whether the labeling or advertising is misleading shall take into account "not only representations made or suggested" by affirmative statements, "but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use" of the drug.

82. At all times material to this Complaint, 21 C.F.R. § 201.57(e) provided as follows, with respect to information to be provided with the sale of Defendants' products:

> Warnings: Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association with a drug; a causal relationship need not have been proved.

83. At all times material to this Complaint, 21 C.F.R. § 200.5 provided as follows:

> Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care. In the public interest, such mail shall be distinctive in appearance so that it will be promptly recognized and read.

84. At all times material to this Complaint, Part 606 of 21 C.F.R. set forth "Current Good Manufacturing Practices" for biological products generally, and 21 C.F.R. § 640, *et seq.*, set forth additional good manufacturing practices for blood and plasma biologicals.

85. At all times material to this Complaint, 21 C.F.R. § 606.140(a) provided:

> Laboratory control procedures shall include: The establishment of scientifically sound and appropriate specifications, standards and test procedures to assure that blood and blood components are safe, pure, potent and effective.

86. At all times material to this Complaint, 21 C.F.R. § 640.60 defined "Source Plasma (1-luman)" as

> the fluid portion of human blood which has been stabilized against clotting, collected by plasmapheresis, and is intended as source material for further manufacture into blood derivatives (a portion of pooled plasma separable by chemical means) intended for injection.

87. At all times material to this Complaint, 21 C.F.R. § 640.63(c), entitled "Qualification of Donor," provided as follows with respect to donors of source plasma:

> Donors shall be in good health on the day of donation, as indicated in part by: . . . (9) freedom from any disease, other than malaria, transmissible by blood transfusion, in so far as can he determined

> by history and examination indicated in this section; (10) freedom of the arms and forearms from skin punctures or scars indicative of addiction to self-injected narcotics; (11) freedom from a history of viral hepatitis; (12) freedom from a history of close contact within six months of donation with an individual having viral hepatitis; . . . .

Further, 21 C.F.R. § 640.63(a) provided that the method of determining "suitability of a donor" included "tests" as well as the taking of a history and physical examination.

88. At all times material to this Complaint, 21 C.F.R. § 606.140 provided as follows:

> Laboratory control procedures shall include: (a) The establishment of scientifically sound and appropriate specifications, standards and test procedures to ensure that blood and blood components are safe, pure, potent and effective.

89. The foregoing statutes and regulations are evidence of the standard of care Defendants should have employed in the manufacture and sale of Factor VIII and Factor IX. Defendants violated the foregoing regulations and/or failed to comply with applicable standards of care by: (a) marketing "adulterated" products that were unsafe as a result of failure to comply with "Current Good Manufacturing Practice"; (b) marketing "misbranded" products that were misleading and failed to disclose or warn of health dangers; (c) failing to warn of serious adverse reactions and potential safety hazards as soon as there was reasonable evidence of an association with the product; (d) failing to exclude intravenous drug users who were unsuitable donors; (e) failing to exclude donors with a history of viral Hepatitis who were unsuitable donors; (f) affirmatively seeking out unsuitable donors known to have viral Hepatitis antibodies, as well as prison populations known to include substantial numbers of intravenous drug users, for inclusion of their plasma in the pools used to make Factor VIII and Factor IX; (g) failing to disclose their use of dangerous donors; and (h) failing to use appropriate tests and/or procedures to assure the products were safe.

I. Conspiracy, Concert of Action and Group Liability

90. Defendants, and each of them, acted in concert and participated in a conscious and deliberate conspiracy to act negligently, fraudulently and with willful and wanton disregard for the rights and safety of blood product users, in connection with the manufacture of Factor VIII and IX blood products and the collection of constituent plasma.

91. Defendants herein tacitly and explicitly agreed to avoid upgrading industry standards. For example, the technology to virally inactivate factor concentrates existed in the early 1970s, but was not seriously investigated by any of the Defendants until the early 1980s, despite its effective use in Europe. Use of the HBc antibody test to eliminate Hepatitis B carrier donors, and to identify donors with a history of viral Hepatitis, was known science by 1978. The HBc test was reported to be an effective surrogate test for both AIDS transmission and NANB Hepatitis carriers by 1982, yet no Defendant implemented this test until April 1984.

92. Defendants used donors from predominantly homosexual donor centers, prisons, and inner city areas where the risk of IV drug abuse was high. After July 1982, when the results of this conduct culminated in reports of fatal immune suppression in three people with hemophilia who infused the product, this concert of action took on a more overt, active form.

93. By December 1982, the FDA demanded that Defendants stop using prisoners, donors from high risk areas for hepatitis and AIDS transmission, and known homosexuals. Rather than use good faith efforts to comply with the FDA requests, Defendants collectively argued for a far less onerous and less effective donor screening program. They jointly proposed a system comprised of educating the donor by posting a placard in the donor center stating who the risk groups for AIDS transmission were, and advising the donor that he would be deferred if he acknowledged he was a member of one of those groups. Later, he would be required to fill out a questionnaire in private. If he checked the box indicating he was in a high risk group, he would be permanently deferred.

94. At a January 6, 1983 meeting of Defendants' trade association, the Biological Section of the Pharmaceutical Manufacturer's Association ("PMA"), Defendants

agreed not to implement highly effective HBc donor screening, instead selecting ineffective donor questionnaires that did little to screen out donors at high risk for AIDS transmission. Defendants further agreed to keep each other informed as to what the other was doing in order that a low standard of care was maintained. HBc testing had been strongly suggested by the CDC at the January 4, 1983 Public Health Service ("PHS") meeting. On January 14, 1983, Defendants acted jointly to persuade the National Hemophilia Foundation ("NHF") not to advocate surrogate testing for AIDS and Hepatitis C through implementation of the HBc test. Defendants persuaded the NHF that use of the HBc test was in the "R and D" stage and not practical to implement at that time.

95. Defendants jointly agreed to oppose recall of the products beginning at the January 6, 1983 meeting at the Pharmaceutical Manufacturers' Association ("PMA"). Beginning with this meeting and continuing through at least July 19, 1983, Defendants met at various times to prepare a strategy to prevent the FDA from advocating a far-reaching recall of factor concentrate products. Defendants knew that due to their high risk donor populations, and their combining of these donors in pools of 5,000 to 40,000, that their products were contaminated with the AIDS agent. Nevertheless, Defendants acted in concert to lobby the FDA, to get the FDA to issue recommendations to limit recalls to circumstances in which an identified donor had died of AIDS within a specified time after the pooling of that donor's plasma. Defendants were well aware that plasma from contaminated asymptomatic donors were mixed in the plasma pools and contaminated virtually all lots. Defendants were successful in deferring any FDA Blood Products Advisory Committee ("BPAC") recommendation for a general recall of the product at the July 19, 1983 BPAC meeting. This joint action allowed the defendants to avoid ever recalling any product except when a donor died of AIDS.

96. Defendants conducted a meeting on or about January 6, 1983 at the PMA, a major purpose of which was to decide on a unified strategy to deal with increasing knowledge of risk of AIDS. At the meeting Defendants agreed to postpone submitting any request to the FDA for permission to amend their warning labels or package inserts. They further agreed not to

apply to the FDA for warnings enhancements until the other three companies agreed to make application for warning enhancements and to make the warnings similar in content. At the time of the meeting, Defendants had been informed by various reliable health authorities, including the PHS, that there was evidence of an association of risk between factor concentrate use and the transmission of AIDS.

97. On December 13, 1983, Stephen Ojala, CUTTER's responsible head, documented by written memorandum that Defendants met and jointly agreed to propose a "study" of the HBc surrogate screening test, as a "delaying tactic" to avoid implementing the HBc test.

98. Thereafter, at various times throughout 1983-1985, Defendants attended meetings or otherwise communicated to assure joint efforts to avoid recalling product; to avoid warning patients of the true risk; to market product when sales dropped due to information in the lay press related to AIDS transmission through factor concentrates; to avoid recall of non-heat-treated product after heat-treated products were available; to avoid implementation of the HBc test; and to coordinate a joint legal defense plan in anticipation of litigation from patients afflicted by AIDS through use of the products. Defendants also operated through trade organizations, such as ABRA and PMA, to issue public statements minimizing the risks of AIDS and Hepatitis C and overpromoting the benefits of factor concentrate, to carry out the above-mentioned goals of all Defendants.

99. All of the Defendants likely to have caused the harms to Plaintiffs are parties to this lawsuit and properly before the court.

100. The conduct of each and all of the Defendants, with respect to their Factor VIII and Factor IX products and related plasma collection methods, was tortious.

101. The harm which has been caused to Plaintiffs resulted from the conduct of one, or various combinations of the Defendants, and, through no fault of the Plaintiffs, there may be uncertainty as to which one or combination of Defendants caused the harm.

102. The burden of proof should be upon each Defendant to prove that the

Defendant has not caused the harms suffered by the Plaintiffs.

103. AHF was manufactured using the same fractionation method by all Defendants. As such, during the relevant years from 1975 until 1985, factor concentrates were a fungible product, and physicians prescribed the products interchangeably without regards to brand names of the drugs.

104. The factor concentrates manufactured by Defendants from 1975 until 1985 contained the same design flaws. They were all manufactured from paid donor plasma, which was at highest risk for Hepatitis B, Hepatitis C, and HIV viral transmission. In addition, the factor concentrate was made from large pools consisting of 5,000 to 40,000 paid donors, which further magnified the risk of viral transmission.

105. None of the factor concentrate was virally inactivated during this time period. Therefore, all of the AHF carried a significant risk of viral transmission. In addition, all of Defendants' factor concentrate products were similarly misbranded. All of the products failed to warn of the known risks enumerated in this complaint.

V. TOLLING OF APPLICABLE STATUTES OF LIMITATION

106. Any and all potentially applicable statutes of limitations have been tolled by Defendants' affirmative and intentional acts of fraudulent conduct, concealment, and misrepresentation, alleged above, which estop Defendants from asserting statutes of limitation. Such acts include but are not limited to intentionally covering up and refusing to disclose use of high risk plasma; sale of products abroad known to be contaminated; suppressing and subverting medical and scientific research; and failing to disclose and suppressing information concerning the risks of HIV and HCV transmission from Defendants' contaminated factor concentrate. For example, while the spread of AIDS in homosexuals and IV drug users became known to the FDA and the public, only Defendants knew that these very populations were the donors Defendants were targeting to obtain plasma for their factor concentrate products.

107. Defendants are estopped from relying on any statutes of limitation because

of their fraudulent concealment and misrepresentation alleged above. Defendants were under a duty to disclose the risks of HIV and HCV transmission from their contaminated factor concentrate because this is nonpublic information over which they had exclusive control, because Defendants knew this information was not readily available to people with hemophilia like Plaintiffs' Decedent, and because this information was relevant to such people in deciding whether to use Defendants' factor concentrate.

108. Until very recently, Plaintiffs had no knowledge that Defendants were engaged in much of the wrongdoing alleged herein. Because of the fraudulent and active concealment of the wrongdoing by Defendants, including but not limited to deliberate efforts—which continue to this day—to give Plaintiffs the materially false impression that Defendants undertook all feasible safety precautions to reduce the risk of HIV and HCV transmission from their contaminated factor concentrate, Plaintiffs could not reasonably have discovered the wrongdoing any time prior to this time, nor could Plaintiffs have, as a practical matter, taken legally effective action given the unavailability, until very recently, of internal memoranda and other documents (as generally described herein) as evidence in support of Plaintiffs' claims. Defendants still refuse to admit and continue to conceal their wrongdoing, and therefore Defendants' acts of fraudulent concealment and misrepresentation continue through the present time.

VI. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

WRONGFUL DEATH

109. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

110. Defendants marketed their Factor VIII and/or Factor IX blood products to and for the benefit of Plaintiffs and Plaintiffs' Decedent, and knew or had reason to know of the defects in their Factor VIII and/or Factor IX blood products, and that Plaintiffs and Plaintiffs'

Decedent would use the blood products.

111. Defendants owed Plaintiffs and Plaintiffs' Decedent duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge, and to produce the blood factor concentrate products in as safe a manner and condition as possible.

112. Specific defects, as specified above in this Complaint, in the blood products, rendered them defective and unreasonably dangerous.

113. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, the Defendants breached their duties to Plaintiffs' Decedent. Such breach exhibited a reckless disregard for the safety of others and willful and wanton conduct.

114. As the direct, producing, proximate and legal cause and result of the Defendants' breach of their duties, Decedent died on or about March 31, 2007.

115. As the direct, producing, proximate and legal cause and result of the Defendant's breach of their duties, Plaintiffs, individually and as a representatives of Decedent, have been injured and have incurred damages, including but not limited to medical and hospital expenses in the past, past physical and mental pain and suffering, and have suffered loss of financial support, goods and services, consortium, and the loss of familial and emotional love and support.

116. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

117. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs and Plaintiffs' decedents and was such as warrants an award of punitive damages.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as follows:

1. For compensatory damages sustained by Plaintiffs, individually and in representative capacity, against all Defendants, jointly and severally, in an amount to be determined at trial;

2. For punitive and exemplary damages according to proof against all Defendants;

3. For an award of prejudgment interest, costs, disbursements and reasonable attorneys' fees;

4. For injunctive relief in the form of an order requiring Defendants to preserve all relevant documents; and

5. For such other and further relief as the Court deems equitable or appropriate under the circumstances.

Dated: March 26, 2008

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DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues stated.

Dated: March 26, 2008

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